DECLARATION OF GILBERT R. GONZALES

I, Gilbert R. Gonzales, hereby state and declare the following:

I am a named inventor on the present application, U.S. Serial No. 10/675,147 ("the '147 Application"), which is assigned to Serene Medical, Inc. of New York, New York. I have B.Sc. (1973) and M.D. (1977) degrees from the University of Arizona. I have performed research in the area of pain, including methods for treating pain by delivery of medications to the intraspinal area via the vertebral venous system, otherwise referred to as Batson's Plexus.

In addition to my research, I belong to the following scientific and medical societies: American Academy of Neurology (Facilitator, Physical Treatments of Chronic Pain, American Academy of Neurology Therapeutics and Technology and Assessment Subcommittee, May, 1992-1996; Member, American Academy of Neurology Continuum Committee on Pain, Kenneth Casey, Facilitator, March, 1994); American Pain Society; Eastern Pain Society; International Association for the Study of Pain; and the Western Pain Society.

I have also served on the following Editorial Boards: American Pain Society Journal, 1993 (ad hoc reviewer); Journal of Pain and Symptom Management, 1993-present (ad hoc reviewer); The Pain Medicine Journal Club Journal, 1994 - expert analyst; Pain Forum, 1999 (ad hoc reviewer); and The Clinical Journal of Pain, 2000 (ad hoc reviewer).

Additionally, I have held the following positions and appointments: Assistant Professor of Neurology, 1990-1992, Department of Neurology, University of Cincinnati School of Medicine, Cincinnati, Ohio; Assistant Professor of Neurology, 1992-

1998 and Associate Professor of Neurology, 1998, Mayo Medical School; Vice Chairman, Department of Neurology, 1994-1998, Mayo Clinic, Scottsdale, Arizona; Assistant Adjunct Professor, 1997-1998, Department of Psychology, University of New Orleans, New Orleans, Louisiana; Associate Attending Neurologist, 1998-2002, Memorial Hospital for Cancer and Allied Diseases, New York, New York; and Associate Member, 1998-2002, Memorial Sloan-Kettering Cancer Center, New York, New York.

I have reviewed the references cited against the claims of the '147 Application, including U.S. Patent No. 5,846,216 (Gonzales). I am a named inventor on the Gonzales reference. Gonzales describes a system for rectal administration of medication into a patient body. Medication is dispensed through a delivery tube and to a dispenser head positioned in the rectum of a patient. When delivered rectally, as in Gonzales, medication must be transported across the rectal mucous membranes and then into the patient's vasculature. The medication thus cannot be directed to a particular vein. Once within the patient's vasculature, an abdominal restraint or binder may be used to increase abdominal pressure to reverse blood flow in Batson's Plexus, thereby delivering some medication into the intraspinal area.

In the present application, I have now developed a system for administering medications by catheterization (or use of a needle or other delivery component) of the pudic vein, the internal pudic vein, or the external pudic vein. Thus, medication can now be directly administered to a patient's intraspinal area via veins that directly communicate with Batson's Plexus (to the exclusion of cross-communication with any other vascular region). However, until the claimed invention of the present application, drugs were not administered intravenously to be directed to the intraspinal

region by increasing intraabdominal pressure to cause reversal of blood flow in Batson's Plexus. And, until the present invention, rectal administration was the only sort of administration of drugs that was successfully used to direct drugs into the bloodstream to thereafter be subjected to reversal of blood flow in Batson's Plexus.

Further, there are several advantages which obtain from catheterization of the pudic vein as in the present invention. For example, pudic vein catheterization allows for the patient to be upright and ambulatory during the dispensing of medication. This contrasts with the rectal dispenser head mucous membrane infusion of Gonzales, wherein a patient must remain recumbent during the dispensing of medication. Further, previous drugs that could not be infused rectally (for example, those with structure too large to cross the rectal mucous membranes) can now be administered by pudic vein delivery. Further, massive drug deliveries can be given through catheterization of the pudic vein. The rectal dispenser head mucous membrane infusion method exhibits an across-the-membrane rate limiting effect, which requires relatively potent drugs to be delivered (due to the relatively low volume per time of infusion). However, through a system including IV pudic vein delivery, one can deliver high volumes of low potency drugs. And further, because the pudic veins directly communicate with Batson's Plexus (to the exclusion of any cross-communication with other vessels), medications may be delivered directly to Batson's Plexus without the medication being diluted by diversion to other vessels. In the previous rectal dispenser head mucous membrane infusion of Gonzales, drugs could not be focused to particular veins (such as the pudic veins), and thus would also enter vessels having cross-communication with other vessels of the body. Given all these advantages, it is my opinion that if the pudic vein catheterization,

and thus IV delivery of medication to the intraspinal region via reversal of blood flow in Batson's Plexus, were obvious, it certainly would have been done previously.

I hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Further Declarant sayeth naught.

August 31, 2006
Date

Gilbert R. Gonzales